

# Implantation of the TandemHeart Percutaneous Left Ventricular Assist Device

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**M**echanical circulatory support is a very powerful therapy that simultaneously improves blood flow and reduces cardiac work. The beneficial effects of this technology were recently demonstrated by the results of the REMATCH trial, which showed a large survival benefit for patients with heart failure who were treated with an implantable left ventricular assist device

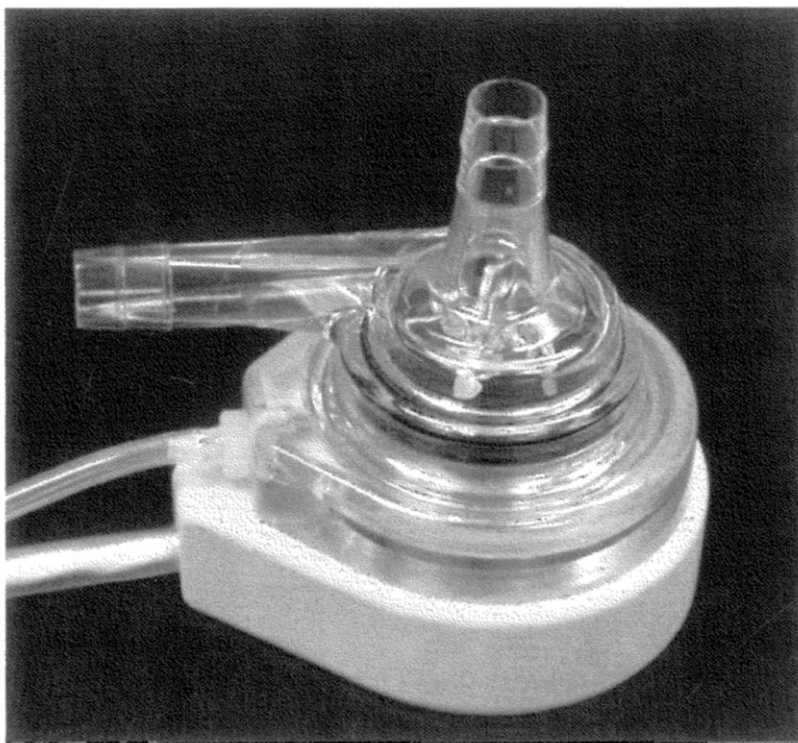
(LVAD).<sup>1</sup> Nonetheless, LVAD therapy typically requires a major surgical operation and the use of expensive technology that limits the therapy to a small group of highly selected individuals.

The TandemHeart (Cardiac Assist Inc., Pittsburgh, PA) is a small centrifugal blood pump that was originally developed as a short-term implantable device called the AB-180.<sup>2-4</sup> The potential therapeutic range of this device was recently expanded by minor modifications that allow percutaneous access for inflow and outflow to an externally located paracorporeal pump.<sup>5</sup> The device has been renamed the TandemHeart, and the percutaneous procedure has been termed percutaneous transeptal ventricular assist. The technique for deployment of the system is described in this article.

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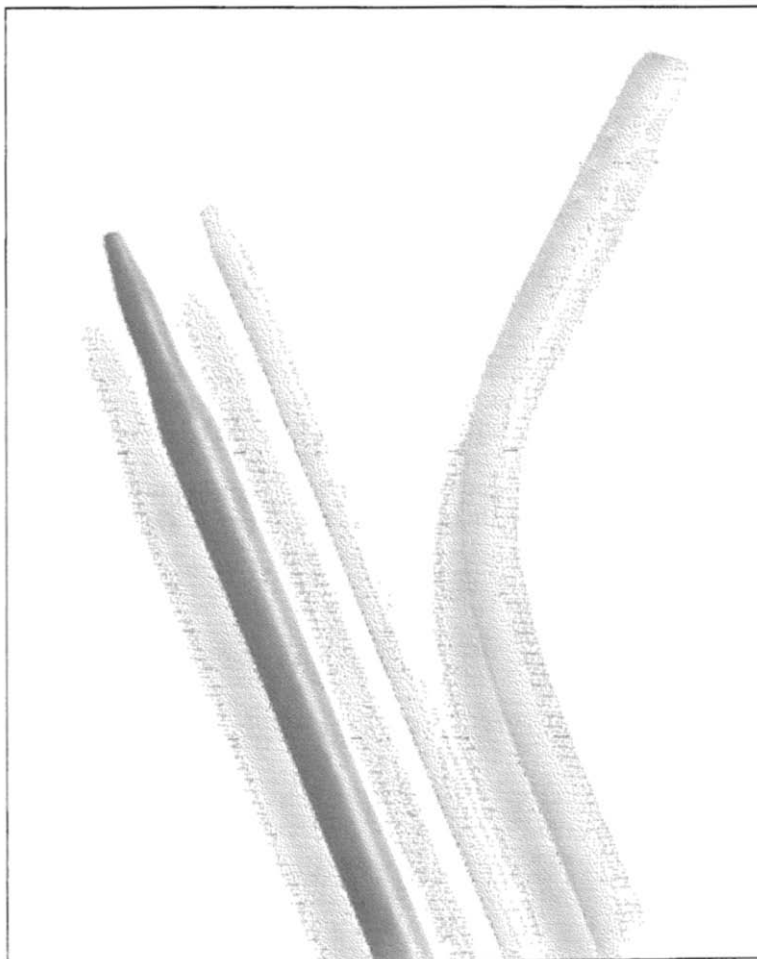
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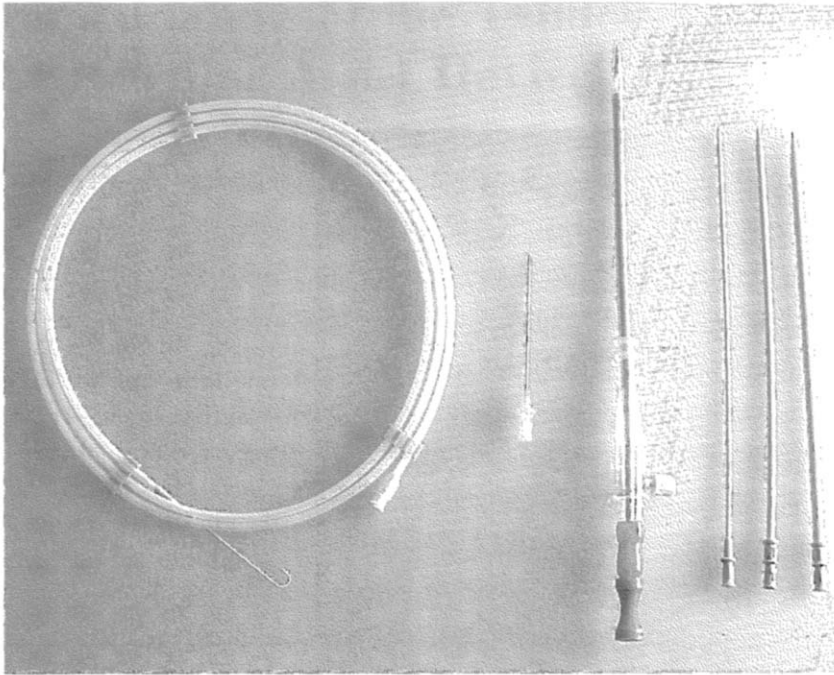
## SURGICAL TECHNIQUE



**1** The photograph shows the TandemHeart pump, which is a small centrifugal pump driven by an electromagnetic motor. On a mock loop, the device can flow up to 10 L/min, but in the clinical setting, the average flow is 3 to 4 L/min owing to limitations from cannula size.

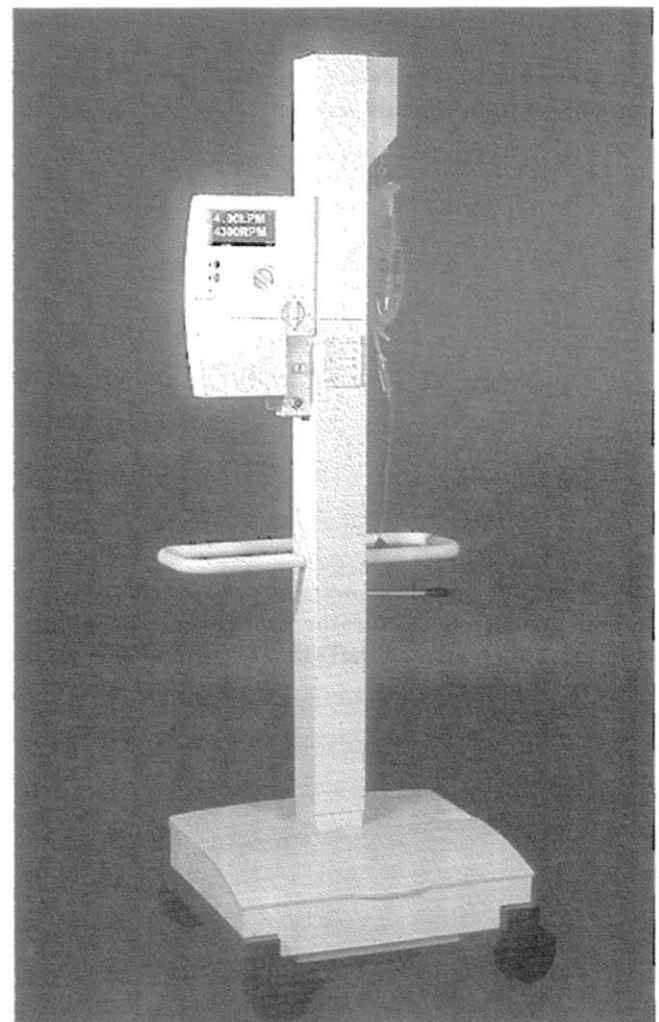
**2** The photograph shows the pre-curved transeptal cannula (right), the obturator for the cannula (middle), and the 2-stage dilator (left) that is used to enlarge the transeptal puncture site.

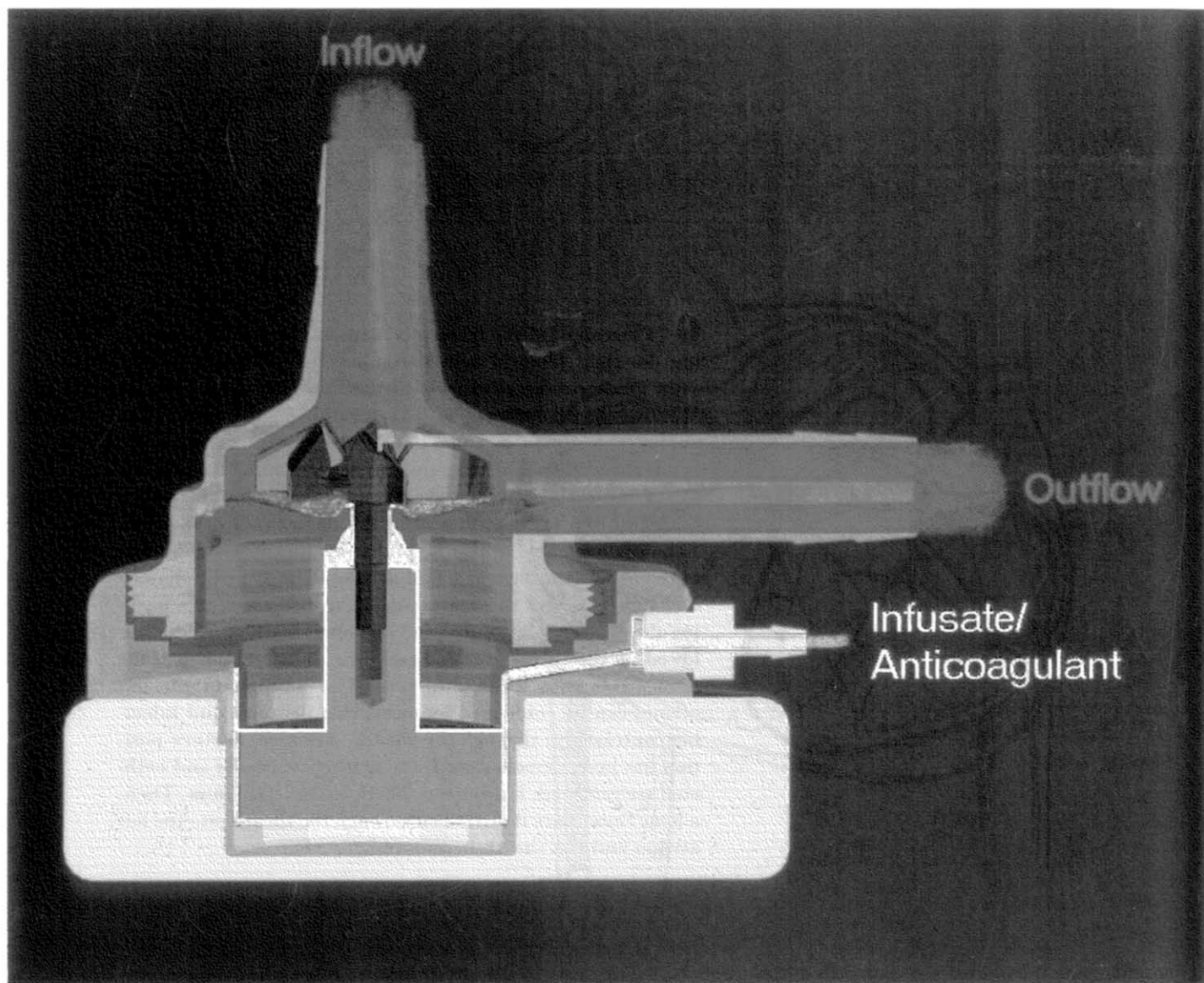




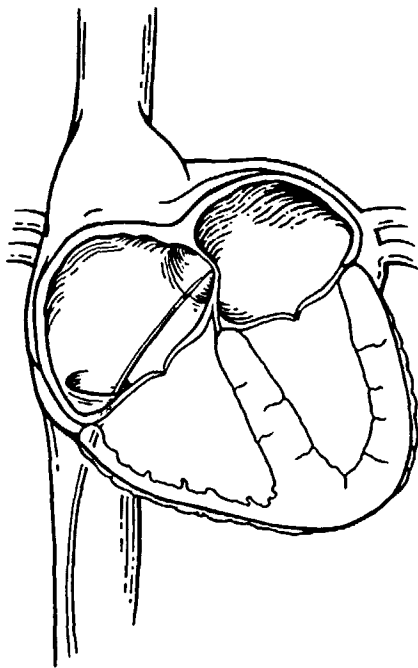
**3** The photograph shows the needle, wire, dilators, and 15-F arterial cannula used to cannulate the femoral artery.

**4** The photograph shows the pump controller, which stands adjacent to the patient bed. The unit is small, compact, and transportable. It also has a built-in back-up unit for use in the case of controller failure. The controller regulates pump speed, the lubrication system, and alarm functions. Operation of the unit is quite simple, consisting of a dial to increase or decrease the revolutions per minute.

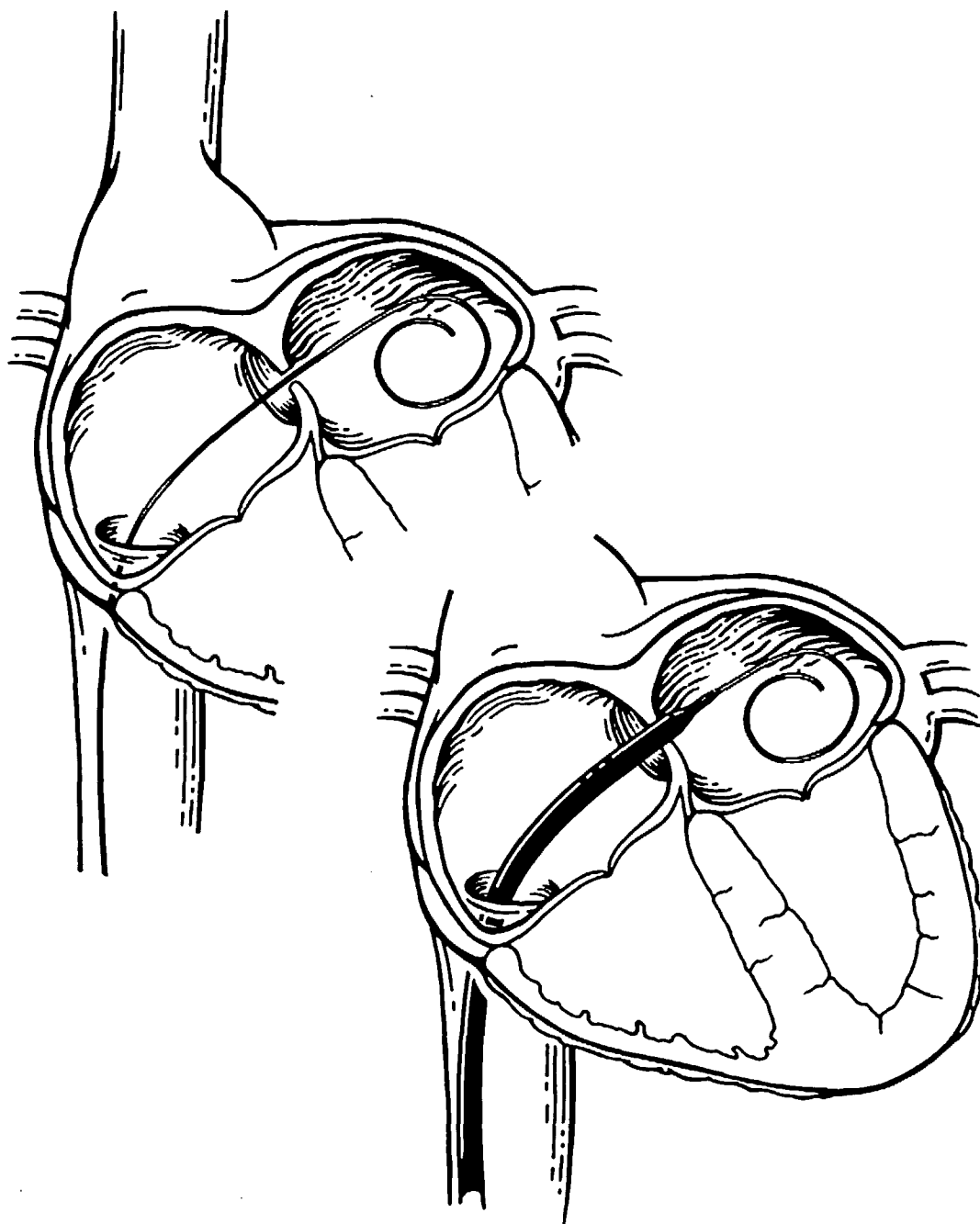




**5** The schematic drawing shows the unique fluid seal that distinguishes this pump from other centrifugal pumps. The lubrication line (yellow) delivers 10 mL/h of heparinized sterile water into the pump, which floats the impeller on the rotor and provides a liquid seal between the upper and lower housing. The delivery of heparinized fluid also allows local anticoagulation within the pump.



**6** Placement of the transeptal cannula begins with accessing the right femoral vein percutaneously. Then a 0.032'' J-tip guidewire is advanced to the superior vena cava. A Mullins sheath/catheter is advanced over the wire. The guidewire is removed, and a Brockenbaugh transeptal needle is advanced through the catheter (not extending beyond the tip of the catheter). The sheath/catheter/needle are pulled back into the right atrium until the fossa ovale is engaged. Echocardiography is also helpful in confirming engagement of the fossa with the transeptal needle. (The drawing shows a 4-chamber view of the heart with the transeptal needle pushing the fossa ovale toward the left atrium.) The needle followed by the catheter and sheath are advanced through the fossa ovale into the left atrium. The position in the left atrium can be confirmed by measuring pressure and injecting contrast dye through the sheath. After satisfactory position has been demonstrated, the transeptal needle and catheter are removed, leaving the sheath in the left atrium. Then, a long Toray wire is advanced through the sheath into the left atrium and the sheath is removed.



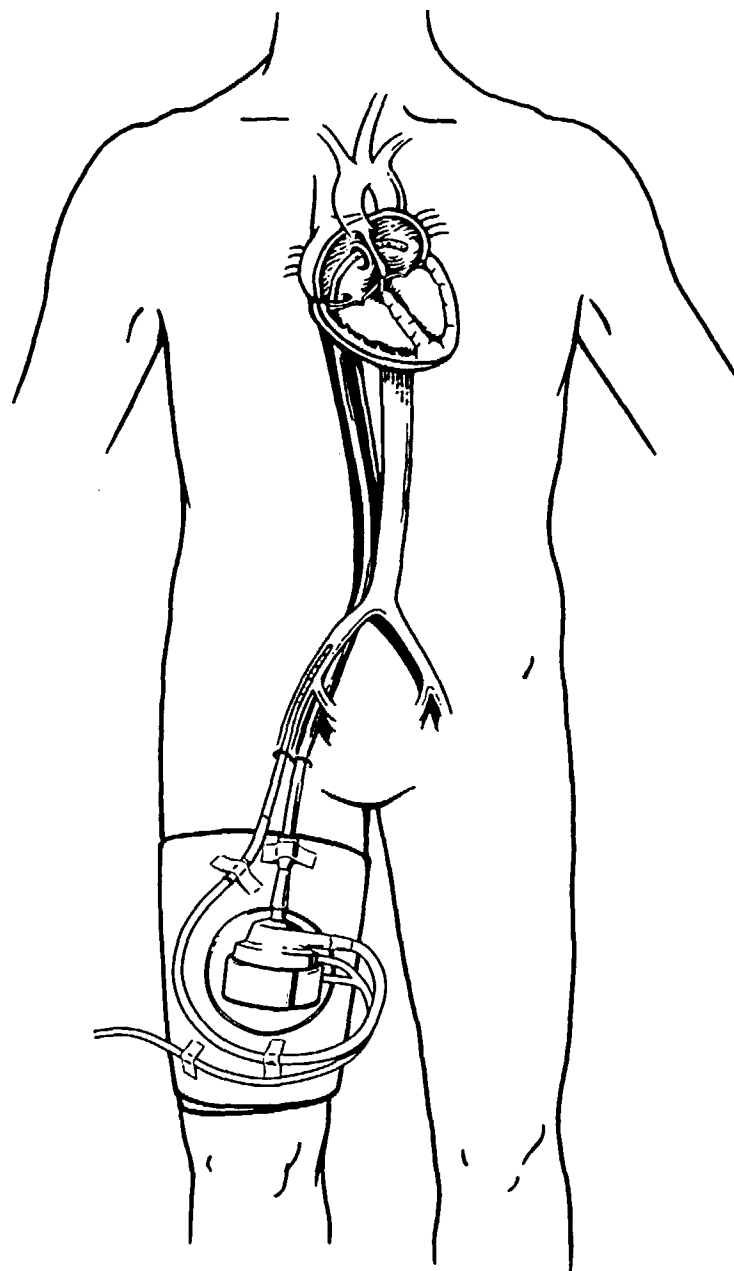
**7** At this point, a looped wire is present in the left atrium, which is shown in the drawing. A graduated 2-stage dilator (14 to 21-F) is then advanced over the wire to dilate the septal puncture site. Next, a 21-F venous cannula is passed over the wire and positioned in the left atrium. The arterial return cannula is inserted into the common femoral artery using the Seldinger technique. Either the right or left side can be used. If a smaller return cannula is necessary because of concerns about distal leg ischemia, two 10-F cannulas can be inserted; one in each femoral artery (not shown).

### Comments

The TandemHeart has been used in over 100 patients as of January 2002. The procedures have been more rapid and less traumatic than open surgical LVAD implantation. Implant times have been less than 45 minutes, and pump flows of 3 to 4 L/min have been routinely achieved. Most patients have a detectable shunt at the atrial level after removal of the cannula, but it often seals spontane-

ously within 6 to 12 weeks. No patients have required surgical closure of an atrial septal defect.

The intended use for the device is in cases of acute heart failure, such as myocardial infarction, decompensated valvular heart disease, or post-cardiotomy shock. The best success occurs when the patient is bridged to definitive therapy, such as revascularization, valve surgery, or an implantable LVAD. The



**8** The drawing shows a patient with the complete system in place. The transeptal cannula can be seen extending from the right femoral vein to the right atrium, and then entering the left atrium. The arterial cannula is also shown in the right femoral artery. The blood pump is attached with a Velcro mechanism to a circumferential bandage around the patient's thigh.

average implant time has been 3 days (range 1 to 14 days), but the device can provide support for several weeks if clinically indicated.

Mechanical circulatory support is a very powerful therapy, but until recently, it has been restricted to a small number of patients because of the need for a major surgical procedure for implantation. There are perhaps 200 cardiac surgeons in the United States with extensive experience in LVAD implantation. This is an insignificant fraction of the number of physicians who deal with acute heart failure. For mechanical circulatory support to be-

come a therapy that is available for all potential patients, more physicians need to be involved, the access procedure has to be simpler, and the devices need to be less costly. Percutaneous transeptal ventricular assist with the TandemHeart fulfills all these criteria. The system is commercially available in Europe and is in a phase II Food & Drug Administration trial in the United States. It is hoped that the TandemHeart will be available in the United States within 1 to 2 years. This will provide an important new tool for cardiac surgeons and interventional cardiologists to deal with acute heart failure.

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